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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,742	10/06/2005	Deborah Addison	JJM0620USPCT	3713

27777 7590 02/07/2007

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
JACKSON, BRANDON LEE	
ART UNIT	PAPER NUMBER
3772	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,742	ADDISON ET AL.	
	Examiner	Art Unit	
	Brandon Jackson	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim 13 is objected to because of the following informalities: "sunthetic polymers" should be "synthetic polymers". Appropriate correction is required.

Claim Objections

Claims 8-10 and 12 are objected to because of the following informalities: claim 1 states a "therapeutic substance" and claims 8-10 and 12 state "therapeutic agent"; 1 phrase should be used in order to stay consistent. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 5-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Kirkwood et al. (U.S. Patent Application Publication 2004/0241214). Kirkwood discloses a wound treatment device (1) comprising a water-impermeable (par 0058) envelope (par 0061) made of a flexible sheet (par 0013 and 0015) having at least one aperture (par 0011) that is blocked by a degradable material (par 0014) that breaks down in the presence of exudates (par 0014) thereby permitting therapeutic substances to pass through the apertures to the wound (par 0011). The total area of the apertures is from about 0.01 to 1 cm^2 (par 0018). The degradable material comprises a substrate for an enzyme present in wound fluid (par 0014). The degradable material comprises a material from the group of polylactide/polyglycolide copolymers, oxidized regenerated cellulose, and mixtures thereof (par 0024). Suitable therapeutic substances include antiseptics such as silver sulfadiazine, chlorhexidine, analgesics, steroids, antibiotics, growth factor, or mixtures thereof (par 0023). The device (1) provides sustained release of therapeutic agent into the wound fluid following the opening of the aperture (par

0048). The therapeutic substance is dispersed in or on a solid substrate (par 0011). The therapeutic substance is dispersed or encapsulated in a bioerodible substance (par 0048) selected from a group comprising proteins, polysaccharides, biodegradable synthetic polymers, glycosaminoglycans and mixtures thereof (par 048). The wound treatment device is packaged in a sterile microorganism-impermeable container (par 0062).

The applied reference has common inventors Breda Cullen and Derek Silock with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kirkwood et al. (U.S. Patent Application Publication 2004/0241214). Kirkwood substantially discloses the claimed invention, see claim 1 rejection above; Kirkwood fails to disclose the envelope having only one aperture. However, the use of only one aperture by applicant serves no critical function, and solves no stated problem. It would have been obvious to one of ordinary skill in the art at the time of the invention to use only one aperture on the Kirkwood device, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold (U.S. Patent 5,759,570) in view of Burton (U.S. Patent 6,903,243). Arnold discloses a wound dressing (1) comprising a water-impermeable envelope (col. 3, lines 49-54). The envelope contains a slow release therapeutic substance (col. 5, lines 4-6) that is released in the presence of wound fluid (col. 4, lines 22-25). The layer containing the therapeutic substance, dispersed on the wound contact layer, is degradable or bio-

absorbable and contains collagen and glycosaminoglycans (col 4, lines 52-53), which also provides a substrate for the enzymes to act upon. The wound dressing (1) also contains microbioside, such as chlorhexidine and maintains a sterile environment for the wound (col. 4, lines 10-14). The wound dressing (1) container is impermeable to micro-organisms (col. 3, lines 58-60). Arnold fails to disclose an aperture, of area about 0.01 to 1 cm^2, in the envelope that is blocked by a degradable material. Also, Arnold fails to disclose that the envelope is flexible. However, Burton teaches a wound dressing (10) with an aperture in the wound facing layer (col. 10, lines 62-64). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Arnold device with the apertured layer over the degradable layer, as taught by Burton, in order to force the exudates towards the absorbent layer and not allow a build up of exudates that may cause the wound dressing to fall off the skin. Applicant fails to disclose that the claimed size aperture provides a specific advantage or solves a stated problem, therefore the Burton aperture size of less than 70% of the thickness absorbent layers would function equally as well. Therefore, it would have been obvious to modify the Arnold/Burton device to have apertures of size about 0.01 to 1 cm^2 because it fails to patentably distinguish the device. Also, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a flexible polymer sheet for the polymer sheet of the Arnold/Burton device because it would prevent the device from tearing or falling off me on a moving wound of a user.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Silcock (WO 02/47737), Samuelsen et al. (U.S. Patent 6,153,215), Ehrnsperger et al. (U.S. Patent 6,160,200), Trotter (U.S. Patent Application Publication 2006/0286155) Cullen et al. (U.S. Patent Application Publication 2005/0159695).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson
Examiner
Art Unit 3772

PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
2/5/07

BLJ